REMARKS

Claims 1, and 4-11 are pending (claims 2 and 3 being canceled by this amendment).

In the aforesaid Office Action, the Examiner rejected claims 1-11 under 35 USC 112, first paragraph, stating, in part, that the limitation "wherein the radiopaque particles are the only metal present in the marker" does not appear to have support in the originally filed application. The limitation has been deleted from claim 1.

The Examiner rejected claims 1-11 under 35 USC 103(a) as being unpatentable over Klein et al. (US 5,776,141) in view of Elliott (US 2003/0164063), stating, in part, that Klein et al. teaches a radiopaque marker comprising a polymer loaded with tungsten radiopaque particles, which is loaded approximately 36 volume percent of the marker since it is 90% by weight, and that although Klein et al. fails to teach adding a wetting agent for facilitating encapsulation of said particles by said polymer and the diameter of the particles, Elliott however teaches that to get the high packing densities required to have loadings as high as 36 volume percent of the composition, the mean particle size is between 1 and 10 microns, and teaches an example in which the median particle diameter is about 10 microns and 90% of the particles have a diameter less than 18.5 microns, and that a wetting agent such as maleic anhydride graft polyolefin is blended with the polymer as a strength enhancing agent. The Examiner states that therefore, it would have been obvious to form the radiopaque particles of Klein et al. with a mean diameter of at least 2 microns and a maximum diameter of about 20 microns in order to maximize the

packing density and be able to form a combination with 36 volume percent radiopaque particles as taught by Elliott, and it would have been obvious to add a maleic anhydride graft polyolefin to a tungsten and polymer mixture/the radiopaque marker of Klein et al in order to enhance the strength of the mixture.

However, Klein et al. in view of Elliott does not disclose or suggest a polymeric marker blend having a wetting agent for facilitating encapsulation of said particles by said polymer, such that the polymer is doped with the radiopaque particles to thereby form a highly radiopaque yet relatively flexible radiopaque marker configured for securing to the intraluminal medical device, wherein <u>a minority of the volume of the marker is metal solids and a majority of the volume of the marker is nonmetal, and the radiopaque particles comprise approximately 36 volume percent of the marker</u>, as required by the embodiment of Applicant's claim 1.

Specifically, modifying Klein et al. in view of Elliott would appear at most to replace the 80-90 wgt. % tungsten in polymeric material of Klein et al. with the tungsten, second metal, binder composition taught by Elliott. Elliott et al. discloses that the tungsten particle size distribution (referred to by the Examiner) is for combining the tungsten with a second metal and a binder to thereby form a highly dense composition as a replacement for lead shot. Elliott thus discloses increasing the <u>packing density</u> of tungsten <u>with a second metal</u> and a binder. Maximizing the packing density thusly would not render obvious only increasing the loading of tungsten in polymer in Klein in the presence of Applicant's particle size distribution (and wetting agent).

Elliott does not disclose that a tungsten particle size of at least 2 microns and a maximum diameter of about 20 microns maximizes the packing density of tungsten to load a polymer with tungsten independently of the second metal of the Elliott composition. Rather, Elliott discloses, and the Examiner refers to, a specific example of the dense, two metal composition of Elliott which is formed with a tungsten particle size distribution D_{90}=18.5. Elliott doesn't teach that the D_{90}=18.5 maximizes the packing density of the tungsten, merely that it is present in the tungsten, other metal, binder mix example. Rather, it is Applicant's specification that discloses that the constrained particle size distribution (as set forth in Applicant's claim 1) facilitates forming a polymer loaded with tungsten which is flexible yet highly radiopaque. Therefore, it would not have been obvious to provide a particle size distribution D_{90}=18.5 for increasing the loading of tungsten in Klein et al. in the absence of the second metal of Elliott. Although Elliott discloses that the tungsten powder is preferably milled to deagglomerate the fine particle clusters that are usually present and to improve the packing density in a tungsten/other metal powder/binder mix, it is unclear from Elliott what specific particle size distribution would improve the packing density of tungsten apart from the teaching in Elliott that the mean particle size is preferably about 0.5-50, more preferably about 1-50, more preferably still 2-20, and more preferably still 1-10 microns in the two metal mixture (which does not disclose or suggest constraining the particle size of tungsten to an average diameter of at least 2 microns and a maximum diameter of about 20 microns).

Similarly, regarding the strength enhancing agent, Elliott et al. discloses that the Fusabond (chemically modified polyethylene) is provided to enhance the strength of the

mixture of tungsten with a second metal and organic binder Elliott does not explicitly disclose a wetting agent. Rather, the Examiner takes the strength enhancing agent provided by a chemically modified polyethylene (e.g., Fusabond.from Dupont) as the equivalent of the wetting agent required by Applicant's claims. However, Elliott discloses that the term "organic binder" refers to all organic components in the composite, and that the strength enhancing agent is the part of that organic binder which enhances the strength of tungsten bound together with a second metal with the organic binder.

Thus, modifying the composition of Klein et al. in view of Elliott to provide the composition with the particle size distribution and strength enhancing chemically modified polyethyelene of Elliott, would not result in a composition having a minority volume percent of metal solids and a majority volume percent nonmetal. Rather, Klein et al. modified to have the resulting high density composition of Elliott has greater than 55 volume percent solids (metals) as taught by Elliott, and thus the metal solids are not a minority of the volume.

Support for the amendment to Applicant's claim 1 can be found at paragraph [0030] disclosing a marker having a general (nonspecific) fill ratio of radiopaque particles in polymer which is 91.3 weight percent (36.4 volume percent), in combination with the disclosure of paragraphs [0021] and [0022] which discuss the general fill ratio in terms of how much solid filler is in the surrounding matrix, and paragraph [0025] which discusses higher general fill ratios of generalized metal/polymer combinations, and paragraph [0027] disclosing a specific example of compounding steps of a mixture for a

radiopaque marker of the invention in which the metal solids present in the resulting mixture consisted of tungsten only. The fill ratio of paragraph [0030] thus would be understood to be the amount of metal solids filling the polymeric composition.

Applicant respectfully requests reconsideration, and issuance of a timely Notice of Allowance.

Respectfully submitted,

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